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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,634	11/25/1997	ELAZAR RABBANI	ENZ-53(D2)	4640
28171 7590 11/27/2012 ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022				
EXAMINER SHIN, DANA H				
ART UNIT		PAPER NUMBER		
1635				
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11/27/2012		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

08/978,634

**Applicant(s)**

RABBANI ET AL.

**Examiner**

DANA SHIN

**Art Unit**

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5) ☒ Claim(s) 275,289,290 and 296-301 is/are pending in the application.
- 5a) Of the above claim(s) 289,290 and 298-301 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 275,296 and 297 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.

- 3) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 7, 2011 has been entered.

### ***Status of Claims***

Claims 275, 289-290, and 296-301 are pending. Claims 289-290 and 298-301 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 2, 2008. Accordingly, claims 275 and 296-297 are under examination on the merits in the instant case.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 275 and 296 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelhardt et al. (US 5,288,609).

Engelhardt et al. disclose a composition comprising two entities, wherein the composition comprises a single-stranded polynucleotide that is hybridized to "a first entity", wherein the "entity" is "a complementary polynucleotide sequence", and the other entity is "a hormone". See claims 30-31. They teach that the single-stranded polynucleotide can be covalently attached to another molecule to form a complex. See column 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a combination product comprising multiple units of the covalently attached single-stranded polynucleotide-hormone complex.

One of ordinary skill in the art would have been motivated to do so in order to increase the number/quantity of hormone delivered to a cell, thereby achieving an additive effective with a single product. Since making a combination product comprising a single-stranded polynucleotide and a hormone, further comprising a complementary single-stranded

polynucleotide was known in the art as taught by Engelhardt et al., and since covalently linking two different elements to form a complex was a known technique as described by Engelhardt et al., one skilled in the art would have had a reasonable expectation of success in arriving at the claimed subject matter. Accordingly, the claims taken as a whole would have been *prima facie* obvious at the time of filing.

Claim 297 is rejected under 35 U.S.C. 103(a) as being unpatentable over Engelhardt et al. (US 5,288,609) as applied to claims 275 and 296 above, and further in view of Osborne et al. (PNAS, 1976, 73:4536-4540, citation of record).

The teachings of Engelhardt et al. are described above, which are fully incorporated herein.

Osborne et al. teach that insulin is a hormone.

It would have been obvious to use the insulin of Osborne et al. for the hormone in the combination product because insulin was an art-recognized hormone at the time of filing. Hence, one skilled in the art desiring to increase the amount of insulin delivered to a cell by a single composition would have been motivated to make a combination product comprising multiple insulin units by adopting the design strategies of Engelhardt et al. Accordingly, the claim taken as a whole would have been *prima facie* obvious at the time of filing.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 275 and 296 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-41 of U.S. Patent No. 5,288,609. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a composition comprising a single-stranded polynucleotide and a hormone, wherein the single-stranded polynucleotide is hybridized to a complementary single-stranded polynucleotide. Since combining two or more compositions having the same functionality to

form a combination product for the same purpose is an obvious design choice for making a more potent or effective product, arriving at the claimed subject matter in the instant case would have been obvious over the reference claims of the '609 patent. Hence, the conflicting claims are not patentably distinct from each other.

Claims 275 and 296 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-29, 44-56, 91-107, 123-134 of U.S. Patent No. 6,221,581 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a composition comprising multiple single-stranded polynucleotides and a ligand (the '581 patent defines the ligand to encompass a hormone), wherein the single-stranded polynucleotide is hybridized to a complementary single-stranded polynucleotide. Since combining two or more compositions having the same functionality to form a combination product for the same purpose is an obvious design choice for making a more potent or effective product, arriving at the claimed subject matter in the instant case would have been obvious over the reference claims of the '581 patent. Hence, the conflicting claims are not patentably distinct from each other. Hence, the conflicting claims are obvious over each other.

Claim 275 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 245-246 of copending Application No. 08/978,633. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a composition comprising a single-stranded polynucleotide and a ligand, wherein the single-stranded polynucleotide is hybridized to a complementary single-stranded polynucleotide. Since combining two or more compositions

having the same functionality to form a combination product for the same purpose is an obvious design choice for making a more potent or effective product, arriving at the claimed subject matter in the instant case would have been obvious over the reference claims of the '633 application. Hence, the conflicting claims are not patentably distinct from each other. Hence, the conflicting claims are obvious over each other.

Claims 275 and 296-297 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 246-252, 255, 264-265, 273-274, 276-281 of copending Application No. 08/978,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a composition comprising a single-stranded polynucleotide and a hormone, wherein the single-stranded polynucleotide is hybridized to a complementary single-stranded polynucleotide. Since combining two or more compositions having the same functionality to form a combination product for the same purpose is an obvious design choice for making a more potent or effective product, arriving at the claimed subject matter in the instant case would have been obvious over the reference claims of the '632 application. Hence, the conflicting claims are not patentably distinct from each other.

### ***Response to Arguments***

Applicant's remarks filed on September 7, 2011 have been fully considered but they are not persuasive. Applicant did not provide rebuttal arguments addressing the '632 ODP rejection, nor filed a signed terminal disclaimer. Hence, the rejection is reiterated.



***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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